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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

08/499,423

Applicant(s)

CAMPBELL ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,14-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,10,14-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5,9,10,14,17,19,20,22-31,33,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (5061276). Tu et al. disclose (col. 12, lines 20,21) a tube with an outer covering, Fig. 2. Tu also discloses the device can be used as a graft, col. 4, lines 53-55. Tu additionally discloses the tube is "essentially" porous, col. 3, lines 4-6. Tu discloses the graft tube is made of polytetrafluoroethylene and has a covering of "essentially" polytetrafluoroethylene, col. 3, lines 45,46. Tu et al. disclose the graft can be sutured to a conduit, col. 5, lines 55-63. Tu also discloses the graft circumference increases as a result of the blood pressure, col. 5, lines 46-48. Tu additionally discloses the tube can be expanded such that the second circumference (10mm) is at least 100% larger than the tube's original circumference (4mm) prior to the application of internal

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pressure, col. 10, lines 34-38. The polytetrafluoroethylene tube is disclosed as having a microstructure of nodes interconnected by fibrils, col. 7, lines 19-22. The circumference is fully capable of being increased by inflating a balloon. Tu also discloses the tube is placed on a tapered mandrel such that it forms a tapered end with a larger circumference at one end and a smaller second circumference at an opposing end, col. 10, lines 33-35. Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Regarding claim 27, it can be construed that an interior liner is present on the graft when multiple layers of PTFE are used, col. 3, lines 35-38.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Eilentropp (4791966). Tu et al. is explained supra. Tu also discloses (col. 11, lines 7-11,col. 12, lines 1-4) that layers of film applied to the tube are helical. However, Tu et al. do not explicitly disclose the PTFE layers are helical. Eilentropp teaches (Fig. 5) that PTFE film (abstract) can be applied helically about a tube. Eilentropp also teaches that helically wrapping prevents leakage, col. 7, line 68, col. 8, lines 1-3. Therefore, it would have been obvious to one of ordinary skill in the art to

apply the PTFE layers helically as taught by Eilentropp about the tube of Tu et al. such that it improves its compatibility and resistance to leakage.

Claims 18,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Hughes et al. (4728328). Tu et al. is explained supra. However, Tu does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Tu et al. in a vessel such as the trachea requiring replacement to the two bronchi.

Claims 3,4,15,16,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Lee (5123917). Tu et al. is explained as before. However, Tu fails to disclose the wall thickness to be less than 0.1mm or use of a stent used to secure the graft to a conduit. Lee teaches that the thickness of the graft equal to about 0.1mm, col. 5, lines 56-59. Lee additionally teaches (col. 5, lines 25-31) a stent is used to secure a graft to a blood conduit, Figs. 1,4. Lee also teaches the stent is used to provide some stiffness to the graft to support the vessel, col. 3, lines 5-9,20-24. It would have been obvious to one of ordinary skill in the art to utilize a stent or stents as taught by Lee in the graft of Tu et al. such that it provides greater support to the vessel it is implanted in. Additionally, the use of a thickness of about 0.1mm for the wall of the graft as taught by Lee in the implant of Tu et al. provides a flexible and small profile for easier delivery to the implantation site.

Response to Arguments

Applicant's arguments filed 10/31/07 have been fully considered but they are not persuasive. Applicant argues that the Tu reference discloses an elastomer layer not required by Applicants' invention. However, as mentioned above Tu discloses an essentially porous PTFE tube and an essentially PTFE film, (col. 3, lines 45,46) since multiple layers are disclosed. It should be noted that since the preamble uses "comprising" permits other elements to be part of an invention found in the prior art. The fact that Tu includes an elastomer layer is a moot point. Applicant also argues that the disclosure of Tu is a misinterpretation of what is taught. However, first the Examiner would like to note that the claims are directed to a product and not a method. Thus, when Tu causes the tube to expand to at least 100% of its original circumference is a moot point so long as Tu discloses this capability and as Applicant admits, the Tu reference does. The claims do not have to be limited to some "finished tube" as alleged by the Applicants.

Applicant's arguments with respect to claims 6,7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE**

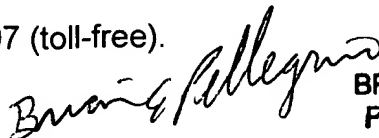
FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 9am to 5:30pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BRIAN E. PELLEGRINO
PRIMARY EXAMINER